

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/486,970 05/23/00 FINBERG

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HM12/0626

EXAMINER

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RUSSEL, J

| ART UNIT | PAPER NUMBER |
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1653

DATE MAILED:

06/26/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|-----------------------|------------------------|
| Application No. | Applicant(s) |
| 09/486,970 | R. Finberg et al |
| Examiner J. Russel | Group Art Unit 1653 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on 5-23-2000.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- Claim(s) 1-17 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-17 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

Art Unit: 1653

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

2. The disclosure is objected to because of the following informalities: At page 1, line 19, "Theses" should be changed to "These". At page 1, line 24, "chemotherapy" is misspelled. At page 2, line 34, "prophylactic" is misspelled. At page 3, line 25, "transfected" is misspelled. At page 5, line 27, "parental" should be changed to "parenteral". At page 5, line 31, "effect" should be changed to "affect". At page 6, line 22, "decrease" should be changed to "decreased". At page 9, line 28, "penicillin" is misspelled. At page 11, line 22, the second period at the end of the line should be deleted. At page 11, line 28, "assess" is misspelled. The specification should be carefully reviewed for other spelling and grammatical errors. Appropriate correction is required.

3. Claims 5 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "analog" in claims 5 and 16 is indefinite because it is not defined either in the description or the art. It is not clear what degree of functional or structural similarity is necessary for one compound to be considered an analog of another compound.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Application/Control Number: 09/486,970

Art Unit: 1653

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to

Application/Control Number: 09/486,970

Art Unit: 1653

reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367

(CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

5. Claims 1-3, 6-9, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertics et al. Bertics et al teach reducing the deleterious effects of endotoxin and endotoxic shock including LPS-induced shock by administering a 2-alkylthioadenosine-5'-nucleotide which blocks both LPS-induced GTPase activity and TNF production. See, e.g., column 2, lines 13-18; column 6, lines 28-34; and column 9, line 67 - column 10, line 6.

6. Claims 10 and 17 are rejected under 35 U.S.C. 103(a) as being obvious over Bertics et al.

Application of Bertics et al is the same as in the above rejection of claims 1-3, 6-9, and 11-14. Bertics et al teach that antibiotic treatment is a current therapy for treating gram negative bacteria, but does not teach the combination of an antibiotic with the nucleotide. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use a combination of the antibiotic and nucleotide taught by Bertics et al to treat gram negative bacteria infection because it is *prima facie* obvious to use a combination of treatments where each treatment has been used individually to treat the same disease and where there is no indication of negative interaction between the treating agents.

7. Claims 1-9 and 11-16 is rejected under 35 U.S.C. 102(b) as being anticipated by Higashijima et al. Higashijima et al teach methods and compositions for modulating the action of G proteins. Mastoparan analogs are used. See, e.g., the abstract and column 7, lines 1-20. With respect to claims 1-9, because the same active agent is being administered to the same subject by

Application/Control Number: 09/486,970

Art Unit: 1653

the same method steps, inherently septic shock will be prevented in Higashijima et al to the same extent claimed by Applicants. With respect to claims 11-16, a suggested use limitation does not impart novelty or non-obviousness to a composition claim where the composition is otherwise taught or suggested by the prior art.

8. Claims 1-9 and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by the Cabeza-Arvelaiz et al article. The Cabeza-Arvelaiz et al article teaches the use of pertussis toxin and cholera toxin to inhibit the effects of LPS. The toxins antagonize LPS activation of G proteins. See, e.g., the Abstract; page 126, lines 12-17 and 24-31; page 128, Table 1; and page 133, lines 6-17. The toxins constitute analogs of mastoparan because of the toxins have the same function and effect as mastoparan in treating or prevent septic shock, and because the claims do not set forth any structural limitations on what constitutes an analog of mastoparan.

9. Claims 10 and 17 are rejected under 35 U.S.C. 103(a) as being obvious over the Cabeza-Arvelaiz et al article. Application of the Cabeza-Arvelaiz et al article is the same as in the above rejection of claims 1-9 and 11-16. The Cabeza-Arvelaiz et al article teaches that antibiotic treatment is a current therapy for LPS-induced shock, but does not teach the combination of an antibiotic with the toxin. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use a combination of the antibiotic and toxin taught by the Cabeza-Arvelaiz et al article to treat gram negative bacteria infection because it is *prima facie* obvious to use a combination of treatments where each treatment has been used individually to

Application/Control Number: 09/486,970

Art Unit: 1653

treat the same disease and where there is no indication of negative interaction between the treating agents.

11. Claims 1-3, 6-9, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by the Proctor et al article. The Proctor et al article teaches administration of 2-methylthio-ATP to protect mice from endotoxic death. The 2-methyl-ATP antagonizes LPS activation of G proteins. See, e.g., the Abstract and page 6020, column 1, Table 1 and first full paragraph.

12. Claims 11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by the Solomon et al abstract (Reference B2 of the Information Disclosure Statement filed August 14, 2000). The Solomon et al abstract teaches G protein agonists or antagonists such as mastoparan. See the entire abstract. Note that a suggested use limitation does not impart novelty or non-obviousness to a composition claim where the composition is otherwise anticipated by or obvious over the prior art.

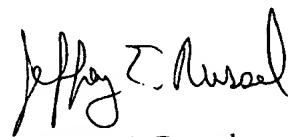
13. Bokoch et al is cited as art of interest, being essentially duplicative of the references applied above.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

Application/Control Number: 09/486,970

Art Unit: 1653

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 305-7401 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1653

JRussel

June 25, 2001